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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,065	01/07/2004	Michael Prencipe	IR 7419-01	6521

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,065	PRENCIPE ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-25* is/are rejected.

7)☒ Claim(s) *16-21 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *24 Mar 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II, drawn to a dental tray, in the reply filed on March 20, 2006 is acknowledged. The traversal is on the ground(s) that upon allowance of the elected invention, the claims are subject to rejoinder. This is not found persuasive because rejoinder is an option if the method claims have the same scope of the claims once the elected claims are deemed allowable.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 20, 2006.

Specification

The disclosure is objected to because of the following informalities: on page 1, line 18 the phrase "by any" is used twice", one should be taken out.

Appropriate correction is required.

Claims

Claim Objections

Claim 15 is objected to because of the following informalities: a period is need at the end of the sentence. Also the term "them" should read "a". Appropriate correction is required.

Claim Rejections - 35 USC § 101/35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claim 22 is rejected under 35 U.S.C. 101, which fails to set forth the statutory class of the invention. The claim recites a dental tray followed by removing the tray and adding a desensitizing agent to the tray. The claim embraces both product and process of using, which violates the rule an invention should set forth the statutory class of invention in the alternative form.

2) Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim purports to be both a product and a process, which makes it ambiguous and therefore does not particularly point out and distinctly claim the metes and bounds the invention.

See Ex parte Lyell 17 USPQ2d 1548.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following claims are indefinite insofar as they lack antecedent basis.

1) Claims 23-24 recite the limitation "said non-aqueous hydrophobic polymer" in the first line of the claims. There is insufficient antecedent basis for this limitation in the claim.

2) Claim 25 recites the limitation "said adhesive enhancing agent" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

The following claims are indefinite insofar as they depend on nonelected claims and therefore are incomplete.

Examination has been conducted on the assumptions as followed:

3) Claim 17 is believed to should read is to read “hydrophobic” not “hydrophilic” based on the specification and the foregoing claims. Appropriate correction is required.

4) Claims 16-17 are believed to should read “claim 15” not “claim 12”.

5) Claims 18-21 are believed to should read, "claim 17" not "claim 14" and "claim 12" respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 15-19 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (WO 01/01939) in view of Chen (US 2003/0129148).

Yu et al. teach compositions for delivering oral care substance such as whitening agents, comprising organosiloxane resin; a volatile carrier capable of solubilizing the organosiloxane resin; and at least one oral care substance. The present invention is also directed to such compositions comprising: an organosiloxane resin, a fluid diorganopolysiloxane polymer; (c) a volatile carrier capable of solubilizing the organosiloxane resin and the fluid diorganopolysiloxane polymer and at least one oral

care substance (page 3, lines 16-24). Silicone resin was used in an amount ranging from preferably from about 20% to about 40% (page 6, lines 5-8). Diorganopolysiloxane polymers that may be included into the compositions have viscosities that span a large range, from about 10 to about 10,000,000 centistokes (cst) at 25°C (page 6, lines 10-20), which would lead one to conclude the resulting compositions would have viscosities within the desired range because of the wide viscosity range of the fluid. The preferred ratio of organosiloxane resin to fluid diorganopolysiloxane-based polymer is preferably from about 4:1 to 6:1 (page 8, line 4). The volatile carrier used in the compositions included volatile silicones (page 8, line 18). Teeth whitening actives included in the compositions include peroxides, e.g., hydrogen, urea, calcium and carbamide peroxide. The bleaching actives comprised 0.1% to 35% of the compositions, which encompasses claims 20-21. Additional components include flavoring agents, which ranged from 0.10 to 1.5% in the examples, and surfactants. Rheology modifiers are incorporated into the compositions and include silicas, polyethylene, and mixtures thereof. They comprise preferably 1% to about 3% of the composition. In the case of adhesive enhancers, the resin or fluid may be considered an adhesive enhancer because when they are mixed together, the adhesiveness of the composition is improved, which encompasses claim 19. The reference differs from the instant claims insofar as it does not disclose applying the compositions with or the compositions being a part of a dental tray.

Chen teaches whitening compositions comprising a peroxide and a water soluble polymer that creates a thick gel with high viscosity. The compositions are applied to the teeth by a dental tray. The dental tray holds the bleach in contact with teeth and

prevents the bleach from flowing away from the teeth to contact soft tissues. Use of a dental tray permits the bleach to remain in intimate contact with teeth for long periods of time without requiring the patient to sit in a dental chair with retracted cheeks. The dental tray also acts as a barrier against dilution of the bleach by saliva and the eventual swallowing of the bleaching material in a short period of time. The reference differs from the instant claims insofar as it does not teach the non-water soluble whitening formulation.

It would have been obvious to one of ordinary skill in the art to have used a dental tray to apply the compositions of the primary reference to the teeth motivated by the desire to avoid contact of the bleaching agent with the soft tissue and also avoid the bleach being diluted by saliva and swallowed, as disclosed by the secondary reference.

In regards to the viscosity range recited by the claims, since the compositions of the reference are substantially the same a hydrophobic polymer; a flavor, an adhesive enhancing agent, a peroxide whitening agent, a surfactant, and other agents, as the Applicant's compositions, they should have the substantially the same properties such as viscosities, as the Applicant's compositions, since they are substantially the same.

2) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (WO 01/01939) in view of Chen (US 2003/0129148) as applied to claims 15-19 and 20-21 above, and further in view of Pfister et al. (US 5,232,702).

The primary reference and the secondary reference are discussed above. The combined references differ from the instant claims insofar as they do not disclose using

a condensation product of silicone resin and organosiloxane as the hydrophobic polymer.

Pfister et al. teach silicon pressure sensitive adhesives comprising a cohesive strengthening agent for transdermal drug delivery. The address the problem of silicone pressure sensitive adhesives, when formulated with or come in contact with co-solvents, excipients, drugs such as nicotine-based drugs, or skin penetration enhancers such as propylene glycolmonolaurate or glycerol monoleate the silicone pressure sensitive adhesive often becomes plasticized, losing tack, adhesiveness, and resistance to flow. A silicone pressure sensitive adhesive composition that solves this problem is a condensation product of a silicone fluid, which is incorporated from about 60 to about 30 parts by weight, and a silicate resin, which is 40 to 70 parts by weight encompassing claim 24, with a cohesive strengthening agent. One of the condensation products used in the example was BIO-PSA, a silicone disclosed by Applicant as a suitable silicone, which encompasses the above weight ratio. By the addition of a cohesive strengthening agent, an improved silicone pressure sensitive adhesive is produced which retains the adhesive on the substrate, without compromising the adhesion of the adhesive to the skin of the patient wearing the bandage or patch. Cohesive strengthening agents include nonionic surfactants, fatty acid esters of glycerol, polysaccharides, carboxypolymethylene, and polyvinylpyrrolidones. These agents are usually incorporated into the composition ranging from 1.0 to 20% weight (col. 7, lines 25-26). The reference differs from the instant claims insofar as it does not disclose using the condensation product and the cohesive strengthening agent in a dental tray.

It would have been obvious to one of ordinary skill in the art to have used the condensation products in the product of the combined primary and secondary references motivated by the desire to enhance adhesiveness of the hydrophobic polymer composition as disclosed by the tertiary reference.

3) Claims 15-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (WO 02/34221) in view of Chen (US 2003/0129148).

Lawlor teaches oral compositions comprising different combinations of polyorganosiloxane gum, polyorganosiloxane resin and a nonvolatile polydimethylsiloxane fluid. In one embodiment the viscosity of the final concentration ranges from 1Pa.s to 1000 Pa.s, which encompasses the instant claims. The gum comprises 0.1% to about 30% by weight of the composition, which encompasses claim 18. The resin comprises 0.5% to 60% of the composition (page 10, paragraph 5). The fluid comprises 0.1% to 95% of the composition (page 15, paragraph 2). The gum to resin ratio is 1:1 to 1:7 and the ratio of gum to fluid is 1:2 to 1:8 (page 7-8), which encompasses claims 23-24. The gum/resin mix creates a hydrophobic surface on the hard and soft tissue of the oral cavity which is able to both prevent build up of plaque and/or deliver oral care actives in a sustained manner (page 6, paragraph 2). This encompasses the instant claims in regards to the hydrophobic polymer specifically claim 23. The compositions also remain fluid (page 5, paragraph 2). The actives used in the compositions include peroxides and percarbonates, which are incorporated in the compositions ranging from 0.1% to 35% (page 17, paragraph 3 and page 18, paragraph

1), which encompasses claims 20-21. In regards to the enhancing agent, the resin or fluid can be considered an enhancing agent because when they are mixed with the gum they make a substantive composition on the oral cavity. In other words they remain on the oral surface after a certain period of time elapses (page 9, paragraph 3). This encompasses claim 19. The composition may also comprise flavoring agents and block polymers of ethylene oxide and propylene oxide, which can be used as an adhesive enhancing agent as recited in claim 25. These components are incorporated into the compositions at concentrations ranging from 0.001% to 10% (page 26, paragraph 1). The reference differs from the instant claims insofar as it does not teach the compositions come in a dental tray.

The secondary reference is discussed above and teaches the using a tray to deliver teeth whitening substances to the teeth. The reference differs from the instant claims insofar as it does not teach the non-water soluble whitening formulation.

It would have been obvious to one of ordinary skill in the art to have used a dental tray to apply the compositions of the primary reference to the teeth motivated by the desire to avoid contact of the bleaching agent with the soft tissue and also avoid the bleach being diluted by saliva and swallowed, as disclosed by the secondary reference.

4) Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (WO 02/34221) in view of Chen (US 2003/0129148) as applied to claims 15-19 and 20-21 above, and further in view of Pfister et al. (US 5,232,702).

The primary and secondary references are taught above. The primary reference teaches the gum to resin ratio is 1:1 to 1:7 and the ratio of gum to fluid is 1:2 to 1:8 (page 7-8), which encompasses claims 23-24.The combined references differ from the instant claims insofar as they do not disclose using a condensation product of silicone resin and organosiloxane as the hydrophobic polymer.

The tertiary reference is discussed above and teaches using condensation products of silicon resin and fluid along with the benefits of using a condensation product as oppose to the combination unreacted. The reference differs from the instant claims insofar as it does not disclose using the condensation product and the cohesive strengthening agent in a dental tray.

It would have been obvious to one of ordinary skill in the art to have used the condensation products in the product of the combined primary and secondary references motivated by the desire to enhance adhesiveness of the hydrophobic polymer composition as disclosed by the tertiary reference.

5) Claims 15-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (WO 02/34221) in view of Allred et al. (US 6,860,736).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not teach the compositions come in a dental tray.

Allred et al. teach an oral treatment device in the shape of a dental tray to deliver sticky, viscous oral compositions to the mouth. The barrier layer of the device protects the oral treatment from saliva during use. It also discusses the advantages of using the

device over strips. The whitening agent may come prepackaged with the tray. The device is simple and easy to use and more reliable to remain in position over the user's teeth, which results in less diffusion of bleaching composition into a user's oral cavity (page 1-2). The reference differs from the instant claims insofar as it does not teach the non-water soluble whitening formulation.

It would have been obvious to one of ordinary skill in the art to have used a dental tray to apply the compositions of the primary reference to the teeth motivated by the desire to make sure the composition remain on the teeth and not leak into the oral cavity as well as making the composition simple and easy to use, as disclosed by the secondary reference.

Claims 15-25 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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